

Application Number 10/731,699
Response to Office Action mailed October 25, 2007

REMARKS

This Amendment is responsive to the Final Office Action dated October 25, 2007.

Applicant has canceled claim 12. Claims 1, 3-11, 13-15 and 17-25 are pending.

Applicant respectfully request entry of this Amendment after the Final Office Action, as it merely cancels one claim.

Claim Rejections Under 35 U.S.C. § 102

Claim 25 (Lynch)

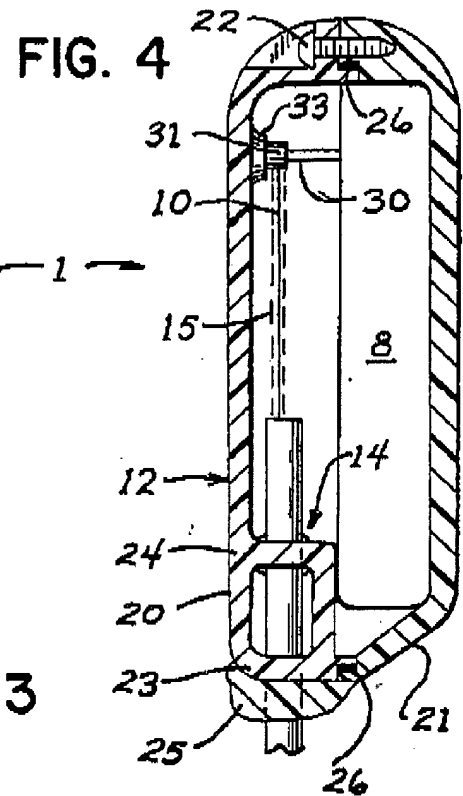
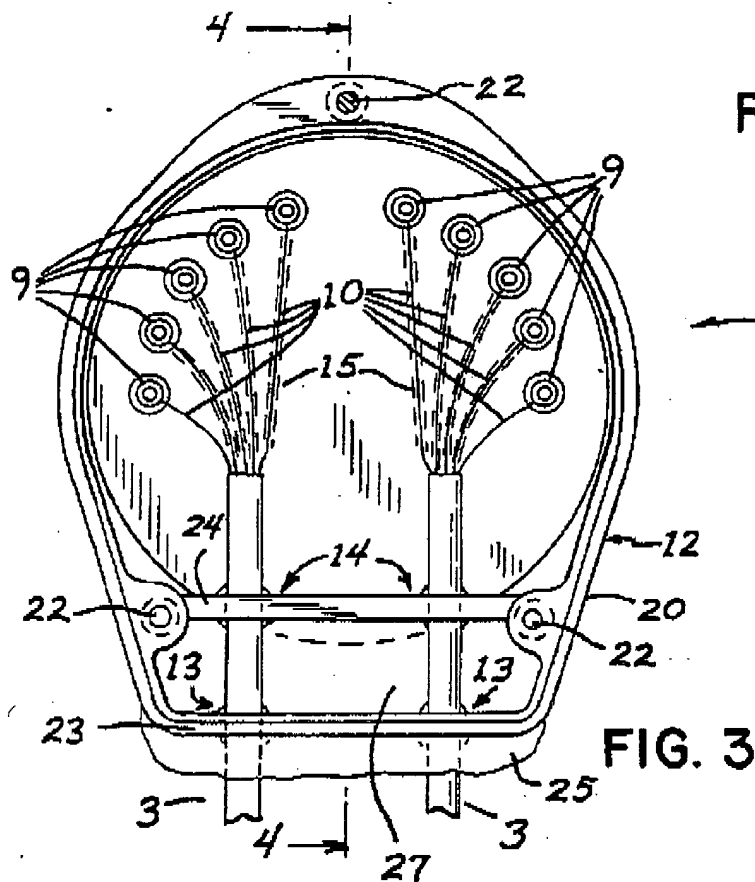
The Office Action rejected claim 25 under 35 U.S.C. § 102(b) as being anticipated by Lynch (US 4,934,368). Applicant respectfully traverses the rejection. Lynch fails to disclose or suggest each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

In the rejection of claim 25, the Office Action cited implant case 12 and nerve cuff 2 of the neurological stimulation apparatus disclosed by Lynch as respectively being equivalent to the first module and the second module recited in claim 25. The Office Action also cited lead 3 as being equivalent to the coupling module as recited in claim 25. The Office Action further stated that lead 3 is inherently hermetically sealed to both implant case 12 and nerve cuff 2 using silicon rubber.

The Office Action failed to cite any support for the contention that lead 3 is inherently hermetically sealed to both implant case 12 and nerve cuff 2 using silicone rubber. Applicant strongly disagrees that such a feature is inherent in the neurological stimulation apparatus disclosed by Lynch. Instead, Lynch actually teaches away from the concept that implant case 12 and nerve cuff 2 are hermetically sealed to lead 3. For example, Lynch discloses that master circuitry case 8 is hermetically sealed, but fails to mention that either implant case 12 or nerve cuff 2 is hermetically sealed to lead 3. For this reason, one of skill in the art would not expect that hermetical sealing of implant case 12 or nerve cuff 2 would be necessary. For reference, FIG. 3 and FIG. 4 of Lynch are reproduced below.

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As mentioned previously, Lynch discloses that master circuitry case 8 is hermetically sealed to protect master circuit 6 from contamination.¹ Lynch then discloses that hermitically sealed master circuitry case 8 is enclosed in implant case 12 and that implant case 12 provides “positive environmental protection” for the termination of the leads 3 into master circuitry case 8 via outer seal 13 and inner seal 14.² Notably, outer seal 13 and inner seal 14 are not described as providing a hermetic seal, but “positive environmental protection.” From this context, one can assume that positive environmental protection refers to a level of sealing different than a hermetic seal. Furthermore, because master circuitry case 8 is disclosed as being hermetically sealed and because master circuitry case 8 is contained entirely within implant case 12, which

¹ Lynch, column 6, lines 20-21.

² Lynch, column 6, lines 40-47.

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provides positive environmental protection, one of skill in the art would assume that positive environmental protection is a level of sealing that is less than hermetic sealing.

Indeed, if implant case 12 were hermetically sealed, then there would be no reason that master circuitry case 8 would need to be hermetically sealed as master circuitry case 8 is contained entirely within implant case 12. Hermetically sealing both implant case 12 and master circuitry case 8 would add unnecessary expense to the manufacture of a neurological stimulation apparatus disclosed by Lynch.

With respect to the connection between lead 3 and nerve cuff 2, Lynch fails to teach or suggest any level of sealing, much less a hermetic connection between lead 3 and nerve cuff 2.

Furthermore, disclosure of Lynch actually demonstrates that silicone rubber does not provide a hermetic seal as asserted in the Office Action. As disclosed by Lynch, implant case 12 includes outer seal 13 and inner seal 14 to provide positive environmental protection at the interface with lead 3. Lynch also discloses silicon rubber 25 outside implant case 12 at the interface with lead 3 for the purpose of absorbing lateral strain on lead 3.³ Lynch fails to mention that silicon rubber 25 has any sealing qualities whatsoever. If silicon rubber 25 provided a hermetic seal as asserted by the Office Action, then outer seal 13 and inner seal 14 would serve no purpose whatsoever. For these reasons, it is apparent that silicon rubber 25 does not provide a hermetic connection between implant case 12 and lead 3. Likewise, the silicon dip coating does not provide a hermetic connection between implant case 12 and nerve cuff 2.

As set out in MPEP 2112 (IV), the Office Action, "must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."⁴ In this case, because the Office Action fails to teach or suggest any reasoning to support the finding of inherency, the current rejection fails to meet this standard. Additionally, the feature of a coupling module hermetically fixed to the first and second housings is clearly not taught or suggested by Lynch.

Lynch fails to teach or suggest each and every element of claim 25. For at least these reasons, the Office Action fails to establish anticipation of Applicant's claims 25 under 35 U.S.C. §102(b). Withdrawal of this rejection is requested.

³ Lynch, column 7, lines 1-6.

⁴ *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

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Claims 7-11, 14, 15, 17 and 20-23

The Office Action rejected claims 7-11, 14, 15, 17 and 20-23 under 35 U.S.C. § 102(b) as being anticipated by Hirschberg et al. (US 5,312,440, hereinafter "Hirschberg"). Applicant respectfully traverses the rejection. Hirschberg fails to teach or suggest each and every feature of the claimed invention, as required by 35 U.S.C. §102 (b), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, with respect to independent claim 7, Hirschberg fails to teach or suggest a coupling module that is made of a metal that defines at least one lumen. In the rejection of claim 7, the Office Action cited lead 9 of Hirschberg as being equivalent to the coupling module as recite in claim 7. However, in contrast to the coupling module recited in claim 7, lead 9 is not made of a metal that defines at least one lumen. Nothing in Hirschberg remotely suggests that lead 9 is made of metal that defines a lumen. Assuming, for the sake of argument, that lead 9 includes metal, e.g., a conductor, such metal does not define a lumen, as required by independent claim 7.

As another example, with respect to independent claim 7, Hirschberg fails to teach or suggest the feature of wherein the coupling module is hermetically fixed to the first and second housings. The Office Action asserts that such a feature would be inherent to prevent bodily fluids from entering and shorting the electrical connections. The Office Action fails to provide any support for this assertion. Applicant respectfully disagrees that hermetic fixation is necessary to prevent shorting of the electrical connections. In the event the Examiner maintains this rejection, Applicant respectfully requests further explanation in this regard as it is not clear to what shorting the Examiner is referring. Furthermore, the Office Action failed to explain why hermetic fixation would be necessary and obvious to prevent shorting.

For example, Hirschberg discloses that terminals 7 and 16, where a first section 18 of lead 9 connects to housings 2 and 15, are in the form of insulated bushings extending through the metal housings 2 and 15.⁵ Presumably these bushings are sufficient to prevent lead 9 from shorting with metal housings 2 and 15, and to prevent bodily fluid from entering housings 2 and

⁵ Hirschberg et al. column 3, lines 31-34.

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15. Hirschberg fails to disclose any additional sealing or insulation regarding the connection of lead 9 and the housings.

Moreover, there is nothing in Hirschberg that suggests that the connection of first section 18 of lead 9 with such bushings 7 and 16 would inherently meet the requirement of claim 7 of a coupling module that is made of a metal that defines at least one lumen and is hermetically fixed to the first and second housings. To the extent the Hirschberg bushings provide any sealing, they would appear to seal the housings 2 and 15 at the point at which a conductor of lead 9 enters, e.g., is fed through, the housings. Thus, any seal would be between the bushings 7 and 16 and the conductor within lead 9. Nothing in Hirschberg would remotely suggest any seal, much less a hermetic seal, between any portion of lead 9 that defines a lumen and either bushings 7 and 16, or housings 2 and 15. Thus, Hirschberg cannot be considered to even suggest, much less inherently disclose, a coupling module that is made of a metal that defines at least one lumen and is hermetically fixed to the first and second housings

Hirschberg fails to teach or suggest each and every element of claim 7. Dependent claims 8-11, 14, 15, 17 and 20-23 are patentable for at least the reasons claim 7 is patentable. Furthermore, dependent claims 8-11, 14, 15, 17 and 20-23 include additional features not found in or suggested by Hirschberg.

For example, with respect to claim 9, Hirschberg fails to teach or suggest a coupling module defining at least two lumens. Hirschberg does not disclose that lead 9 includes at least two lumens.

Similarly, with respect to claim 10, Hirschberg fails to teach or suggest a coupling module defining two coaxial lumens. Nothing in Hirschberg remotely suggests that lead 9 includes coaxial lumens, as required by claim 10.

As another example, with respect to claim 14, Hirschberg fails to teach or suggest a coupling module including at least one of a corrugation, convolution, and a variation in cross-sectional shape.

As another example, with respect to claim 15, Hirschberg et al. fails to teach or suggest a coupling module including at least a helical portion. Nothing in Hirschberg remotely suggests that lead 9 includes a helical portion, as required by claim 15. The figures in Hirschberg do not depict lead 9 as including a helical portion.

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As another example, with respect to claim 17, Hirschberg et al. fails to teach or suggest a coupling module made of a metal comprising titanium. Hirschberg mentions that housings 2 and 15 may consist of titanium,⁶ but certainly fails to consider that lead 9 may be made of a metal comprising titanium that defines at least one lumen.

Because many features recited in the dependent claims are not addressed in the Office Action, Applicant was unable to provide a detailed and reasoned response to rebut the rejections. Applicant points out that the Examiner is required to provide "reasons for [a] rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application."⁷ Applicant submits that the rejections regarding dependent claims 8-11, 14, 15, 17 and 20-23 fail to meet this standard. In the event the rejections are not withdrawn, Applicant respectfully requests greater detail in subsequent office actions or any advisory action regarding such rejections. In particular, the Applicant requests that subsequent actions correlate the specific elements in the prior art to features recited in the Applicant's claims.

The Office Action fails to establish anticipation of claims 7-11, 14, 15, 17 and 20-23 under 35 U.S.C. § 102(b). Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 103

Claims 1, 3-6 and 24 (Lynch)

The Office Action rejected claims 1, 3-6 and 24 under 35 U.S.C. § 103(a) as being unpatentable over Lynch (US 4,934,368). Applicant respectfully traverses the rejection. The applied reference fails to teach or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Lynch fails to teach or suggest an implantable medical device comprising at least two modules, each of the modules comprising a respective one of at least two housings, a coupling module coupled to each of the modules, the coupling module defining at least one lumen between the housings, and an overmold that at least partially encapsulates each of the housings

⁶ Hirschberg et al., column 3, lines 31-32.

⁷ 35 U.S.C. 132(a).

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and the coupling module, wherein the coupling module permits motion of the two modules along at least one axis of motion.

In the rejection of claim 1 the Office Action admits that Lynch fails to teach an overmold that at least partially encapsulates each of the housings and the coupling module as recited in claim 1. However, the Office Action argued that it would be obvious to coat both the case 12 and the lead 3 with a dip coating of silicone because Lynch teaches the layer of soft silicon 25 is applied after the lead and the case have been assembled and because a dip coating is also an after an assembly process. For reference, a portion of Lynch that discusses silicon 25 is shown below.

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At the point where the leads 3 enter the case 12, a layer of soft silicone rubber 25 is applied to absorb any lateral strain on the leads 3. This layer of soft silicone 25 is applied after the case 12 and leads 3 have been assembled and can be removed, for example, by cutting, if a lead 3 needs to be replaced.

The Office Action fails to provide any reasoning whatsoever as to why one of ordinary skill in the art would find it obvious to modify silicon 25 other than to say that, "a dip coating is also an after an assembly process." Lynch fails to provide any reason to include more silicon than that shown in FIG. 3, which is what the Examiner proposes. In fact, Lynch teaches a benefit of the layer of silicon 25 that may not be the same with a dip coating— the benefit that the layer of silicon 25 can be removed if a lead 3 needs to be replaced. In contrast, a dip coating of silicon on each of cuff 2, lead 3 and case 12 would likely be more difficult to remove than a layer of silicon 25 only where lead 3 enters case 12, which could make it more difficult to replace a lead.

Furthermore, because a dip coating on each of cuff 2, lead 3 and case 12 would be more extensive than a dip coating at cuff 2 and a separate layer of silicone 25 at only where lead 3 enters case 12, it may not provide the same advantages or serve the same purposes as the dip coating at cuff 2 and the separate layer of silicone 25 at only where lead 3 enters case 12. For example, a dip coating on each of cuff 2, lead 3 and case 12 may not absorb lateral strain on leads 3 in the same way as a separate layer of silicone 25 at only where lead 3 enters case 12. In this manner, the modification proposed by the Examiner may frustrate the intended purpose of the separate layer of silicone 25 at only where lead 3 enters case 12. Because there is no logical reason to undertake the modification proposed in the Office Action, and because it may

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negatively affect the ability of Lynch device to operate as intended, a person of ordinary skill in the art would not have undertaken such medication or considered it obvious.

In this manner, Lynch fails to teach or suggest Applicant's invention as recited in claim 1. Dependent claims 3-6 and 24 are patentable for at least the reasons claim 1 is patentable. Furthermore, dependent claims 3-6 and 24 include additional features not found in or suggested by Hirschberg et al.

For example, with respect to claim 4, Lynch fails to teach or suggest a coupling module defining at least two lumens. For example, Lynch does not disclose that lead 3 includes at least two lumens. Indeed, the Office Action fails to even address this feature.

As another example, with respect to claim 6, Lynch fails to teach or suggest the feature of wherein the implantable medical device has a maximum thickness of between approximately 4 millimeters and approximately 8 millimeters. Again, the Office Action fails to even address this feature.

For at least these reasons, the Office Action fails to establish a prima facie case for non-patentability of Applicant's claims 1, 3-6 and 24 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

Claims 12, 13, 18 and 19 (Hirschberg et al.)

The Office Action rejected claims 12, 13 and 17-19 under 35 U.S.C. §103(a) as being unpatentable over Hirschberg. Applicant notes that claim 12 is now cancelled, rendering its rejection moot. Applicant respectfully traverses the rejection of claims 13, 18 and 19. The applied reference fails to teach or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention. Applicant notes that claims 13, 18 and 19 are patentable for at least the reasons independent claim 7 is patentable.

For example, with respect to independent claim 7, Hirschberg fails to teach or suggest the feature of wherein the coupling module is made of a metal that defines at least one lumen. As another example with respect to independent claim 7, Hirschberg fails to teach or suggest the feature of wherein the coupling module is hermetically fixed to the first and second housings.

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In addition, claims 13, 18 and 19 include features also not taught or suggested by Hirschberg. As an example, claim 13 recites the feature of wherein the coupling module includes a bellows section. First, Hirschberg fails to disclose a bellows section. For this reason alone, the rejection of claim 13 should be withdrawn. Additionally, a bellows section would serve no purpose in the implantable defibrillator disclosed by Hirschberg et al. In the rejection of claim 13, the Office Action stated that it would have been obvious to included a bellows section to permit axial flexibility the implantable defibrillator disclosed by Hirschberg et al. However, leads 9 presumably include a plastic or like coating over a flexible metal conductor. Unlike the coupling module is made of a metal that defines at least one lumen as recited in claim 7, leads 9 would likely have axial flexibility without the inclusion of a bellows section. For at least these reasons, the feature of wherein the coupling module includes a bellows section would not have been obvious to one of ordinary skill in the art and the rejection of claim 13 should be withdrawn.

As another example, claim 18 recites the feature of wherein the coupling module is fixedly coupled to at least one housing with a weld joint. In the rejection of claim 18, the Office Action stated that it would have been obvious to weld titanium to make a hermetic seal to prevent corrosion and seal out bodily fluids in the implantable defibrillator disclosed by Hirschberg et al. However, leads 9 are not made of metal forming a lumen, much less titanium, and it is not clear how welding could be used without damaging the leads, which presumably include a plastic coating or the like covering a metal conductor.

For at least these reasons, the Office Action fails to establish a prima facie case for non-patentability of claims 13, 18 and 19 under 35 U.S.C. §103(a). Withdrawal of this rejection is requested.

Claims 7, 8, 19 and 25 (Meltzer)

The Office Action rejected claims 7, 8, 19 and 25 under 35 U.S.C. §103(a) as being unpatentable over Meltzer (US 5,645,586). Applicant respectfully traverses the rejection. The applied reference fails to teach or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

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In the rejection of independent claim 7, the Office Action correctly recognized that Meltzer fails to teach or suggest a coupling module that defines at least one lumen between the first and second housings. Nonetheless, the Office Action concluded that such a feature would have been obvious. Applicant respectfully disagrees.

A finding of obviousness under 35 U.S.C. §103(a) requires that all of the claimed elements were known in the prior art.⁸ In this instance, the Office Action freely admits that each of the claimed elements were not found in the cited reference and fails to provide any indication that the claimed elements not found in the cited reference were known in the prior art. Therefore, the rejection of independent claim 7 under 35 U.S.C. §103(a) as being unpatentable over Meltzer is improper and should be withdrawn.

Additionally, the mere fact that Meltzer mentions that the manner in which housing segments may be joined takes many forms as cited in the Office Action is completely insufficient to provide support for a prima facie case of obviousness regarding the feature of a coupling module is made of a metal that defines at least one lumen between the first and second housings as recited by claim 7. Meltzer clearly fails to disclose or suggest such a feature.

In light of the obvious differences between claim 7 and Meltzer, Applicant reserves further comment with respect to dependent claims 8, 19 and 25.

For at least these reasons, the Office Action fails to establish a prima facie case for non-patentability of claims 7, 8, 19 and 25 under 35 U.S.C. §103(a). Withdrawal of this rejection is requested.

Rejection for Obviousness-type Double Patenting

The Office Action rejected claim 1 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending US Pat. No. 7,212,864.

Applicant respectfully traverses this rejection. Applicant respectfully submits that the Office Action has not established a prima facie case of obviousness-type double patenting. To support an obviousness-type double patenting rejection, the Office Action must assess the differences between the claims in the pending application and the claims in the issued patent.⁹ In

⁸ *KSR*, 550 U.S. at ___, 82 USPQ2d at 1395, as cited in MPEP 2143.

⁹ *In re Berg*, 46 USPQ2d 1226, 1229 (Fed Cir. 1998).

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particular, the Office Action should indicate why the claims in an application are obvious over the claims in the granted patent.¹⁰

The Office Action stated that the application and patent claims are not patentably distinct "because the two modules of the claimed invention possess an identical housing to that of the [issued patent]." Proper analysis employed in an obviousness-type double patenting rejection is the same as analysis for a 35 U.S.C. §103 obviousness determination.¹¹ Therefore, all of the claimed features recited by claim 1, in combination, must be obvious in view of claim 1 of US Pat. No. 7,212,864.

In contrast to the present invention as recited in claim 1, claim 1 of US Pat. No. 7,212,864 does not include or suggest, "a coupling module coupled to each of the modules, the coupling module defining at least one lumen between the housings," as recited in claim 1 of the present application. Because each of the features of claim 1 are not obvious in view of claim 1 of US Pat. No. 7,212,864, Applicant respectfully requests that the Examiner withdraw this rejection.

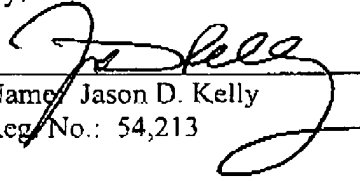
CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: January 25, 2008

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¹⁰ *Id.*

¹¹ *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985), as cited in MPEP 804.